

Lot No.: **16F**

Lot-specific Information

***Olerup SSP[®]* DQA1**

Product number:	101.231-24u/04u – without <i>Taq</i> pol.
Lot number:	16F
Expiry date:	2010-October-01
Number of tests:	24 tests – Product No. 101.231-24u 4 tests – Product No. 101.231-04u
Number of wells per test:	32
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 16F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP[®]* DQA1 Lot

The DQA1 specificity and interpretation tables are unchanged compared the previous *Olerup SSP[®]* DQA1 lot (**Lot No. Y46**), as no new DQA1 alleles have been described since the previous lot was made.

The DQA1 primer set is unchanged compared to the previous lot (**Lot No. Y46**).

Change in revision R01 compared to R00:

1. The DQA1*0509 allele is weakly amplified by primer mix 25.

Lot No.: **16F**

Lot-specific Information

PRODUCT DESCRIPTION

DQA1 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQA1*0101 to DQA1*0602 alleles.

STRIP LAYOUT

Each test consists of 32 PCR reactions in a 32 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32

The 32 well cut PCR plate is marked with 'DQA1', in silver/gray ink.

Well No. 1 is marked with the Lot No. '16F'.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 32 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only DQA1 alleles will be amplified by the DQA1 typing kit. Thus, the interpretation of DQA1 typings is not influenced by the DQA2 gene.

UNIQUELY IDENTIFIED ALLELES

All the DQA1 alleles, i.e. **DQA1*0101 to 0107, DQA1*0201, DQA1*0301 to 0303, DQA1*0401 to DQA1*0404, DQA1*0501 to 0509 and DQA1*0601 to DQA1*0602**, recognized by the HLA Nomenclature Committee in October 2008¹ will give rise to unique amplification patterns by the primers in the DQA1 typing kit.

The DQA1 typing kit cannot distinguish the DQA1*010101 and 010102 alleles, the DQA1*010201 to 010203 alleles, the DQA1*010401 and 010402 alleles, the DQA1*050101 and 050102 alleles and the DQA1*060101 and 060102 alleles.

¹DQA1 alleles listed on the IMGT/HLA web page 2008-October-10, release 2.23.0, www.ebi.ac.uk/imgt/hla.

Lot No.: **16F**

Lot-specific Information

RESOLUTION IN HOMO- AND HETEROZYGOTES

The DQA1 alleles give rise to 28 different amplification patterns, the DQa1*010201-010203 and 010204 alleles and the DQA1*040101 and 040102 alleles have different amplification patterns, which can be combined in 406 homozygous and heterozygous combinations. Twenty-seven of these genotypes do not give rise to unique amplification patterns.

++--++--	----+---	-----+	-----	0104, 0104 = 0104, 0105
++-----+	-----++-	+--+---+	+-----	0101, 0509 = 0107, 0505
				= 0107, 0509
++-----+	----+---	-----+	+-----	0101, 0107 = 0107, 0107
-++-----+	----+---	-----+	-----	0102, 0106 = 0106, 0106
-----+	-+++-----	-----+	-----	0302, 0302 = 0302, 0303
-----+	-----++++	+--+---+	-----	0501, 0502 = 0502, 0502
-----+	-----++++	+--+---+	+-----	0505, 0509 = 0509, 0509
-----+	-----++++	+--+---+	-----+	0505, 0508 = 0508, 0508
-----+	-----++++	-++-----+	-----+-	0503, 0506 = 0506, 0506
-----+	-----++++	-++-----+	-----+-	0503, 0507 = 0507, 0507
-----+	-----++-	-----++	-+-----	0401, 0402 = 0402, 0402
-----+	-----++-	-----++	---+-----	0401, 0404 = 0404, 0404
-----+	----+---	-----++++	-----+-	0601, 0602 = 0602, 0602

Lot No.: **16F**

Lot-specific Information

SPECIFICITY TABLE

DQA1 SSP typing

Specificities and sizes of the PCR products of the 32 primer mixes used for DQA1 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DQA1 alleles ³
1⁴	145 bp	515 bp	010101-010102, 010401-010402, 0105, 0107
2	170 bp	515 bp	010101-010102, 010201-010204, 010401-010402, 0105, 0106, 0107
3⁴	145 bp	430 bp	010201-010204, 0103, 0106
4	170 bp	430 bp	0103
5	220 bp	430 bp	010401-010402, 0105, 0106 [?] , 0107 [?]
6⁴	100 bp	430 bp	010401-010402, 0106 [?] , 0107 [?]
7⁴	95 bp	430 bp	0106
8⁴	65 bp	430 bp	010101-010203, 0103, 0106 [?] , 0107 [?] , 0201-0602
9	175 bp	430 bp	0201
10	185 bp	430 bp	030101, 0302, 0303
11⁵	215 bp	430 bp	0302
12⁵	225 bp	515 bp	0302, 0303
13	225 bp	515 bp	010101-030101, 040101, 0402-0602
14⁴	125 bp	430 bp	040101-040102, 0402, 0404, 050101-0509
15	165 bp	430 bp	050101-0509
16⁴	90 bp	430 bp	0502
17⁵	200 bp	430 bp	050101-050102, 0502 [?] , 0504 [?] , 0505, 0508, 0509
18⁵	200 bp	430 bp	0502 [?] , 0503, 0504 [?] , 0506, 0507
19	205 bp	430 bp	050101-0503, 0505-0509
20⁴	130 bp	430 bp	0504
21^{4,5,6}	110 bp	430 bp	0502 [?] , 0504 [?] , 0505, 0508, 0509
22⁴	110 bp	515 bp	060101-060102, 0602
23^{4,5}	85 bp	430 bp	040101-0404, 060101-0602
24⁵	240 bp	430 bp	010101-0107, 0201 ^{weakly} , 030101, 0302-050102, 0502 [?] , 0503, 0504 [?] , 0506, 0507, 060101-0602
25⁷	175, 275 bp	430 bp	0107, 0509 ^{weakly}

Lot No.: **16F**

Lot-specific Information

26	150 bp	430 bp	0402
27^{4,5}	90 bp	430 bp	0403N
28⁴	105 bp	430 bp	0404
29	160 bp	430 bp	0602
30	215 bp	430 bp	0506
31^{4,5}	100 bp	430 bp	0507
32⁴	135 bp	430 bp	0508

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of DQA1 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective length of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers, e.g. the primers in wells 11, 12, 17, 18, 21, 23 and 27.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQA1 typing.

In addition, wells number 2, 12, 13 and 22 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³For several DQA1 alleles only partial 1st, 2nd, 3rd and 4th exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences are conserved within allelic groups.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵Primer mixes 11, 12, 17, 18, 21, 23, 24, 27 and 31 may give rise to nonspecific amplifications.

⁶Primer mix 21 may yield somewhat less specific PCR product than the other DQA1 primer mixes.

⁷Primer mix 25: Specific PCR product of 175 bp in the DQA1*0107 allele. Specific PCR product of 275 bp in the DQA1*0509^{weakly} allele.

'?', nucleotide sequence information not available for the primer matching sequence.

Lot No.: **16F**

Lot-specific Information

INTERPRETATION TABLE																
DQA1 SSP typing																
Amplification patterns of the DQA1*0101 to *0602 alleles																
	Well5															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	145	170	145	170	220	100	95	65	175	185	215	225	225	125	165	90
PCR product																
Length of int.	515	515	430	430	430	430	430	430	430	430	430	515	515	430	430	430
pos. control ¹																
5'-primer(s) ²	34	25	34	25	-7	199	25	-7	7	7	-6	99	99	25	34	59
	5'-Ag g ³	5'-g TA ³	5'-Ag C ³	5'-g TT ³	5'-CC A ³	5'-gC A ³	5'-g TA ³	5'-CC g ³	5'-CAC ³	5'-CAT ³	5'-g AC ³	5'-CCC ³	5'-CCC ³	5'-g TA ³	5'-Ag C ³	5'-C Cg ³
								-7								
								5'-CC g ³								
3'-primer(s) ³	69	69	69	69	1 st in	218	44	2	52	55	1 st in	160	160	53	75	75
	5'-TgC ³	5'-TgC ³	5'-TgC ³	5'-TgC ³	5'-TTT ³	5'-C TT ³	5'-AgC ³	5'-T gT ³	5'-T gT ³	5'-TCT ³	5'-TTT ³	5'-C AT ³	5'-C Ag ³	5'-TTg ³	5'-g AC ³	5'-g AC ³
													160			
													5'-C Ag ³			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DQA1 allele ⁴																
*010101-010102	1	2						8					13			
*010201-010203		2	3					8					13			
*010204		2	3										13			
*0103			3	4				8					13			
*010401-010402	1	2			5	6							13			
*0105	1	2			5								13			
*0106		2	3		?	?	7	?					13			
*0107	1	2			?	?		?					13			
*0201								8	9				13			
*030101								8		10			13			
*0302								8		10	11	12				
*0303								8		10		12				
*040101								8					13	14		
*040102								8						14		
*0402								8					13	14		
*0403N								8					13			
*0404								8					13	14		
*050101-050102								8					13	14	15	
*0502								8					13	14	15	16
*0503								8					13	14	15	
*0504								8					13	14	15	
*0505								8					13	14	15	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



Lot No.: **16F**

Lot-specific Information

INTERPRETATION TABLE															
DQA1 SSP typing															
Amplification patterns of the DQA1*0101 to *0602 alleles															
Well5															
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
200	200	205	130	110	120	85	240	175	150	90	105	160	215	100	135
								275							
430	430	430	430	430	515	430	430	430	430	430	430	430	430	430	430
107	107	21	21	-13	25	32	up ⁶	up ⁶	101	53	153	99	102	188	107
5'-C AT ³	5'-C AT ³	5'-T CC ³	5'-T CT ³	5'-gg A ³	5'-g TT ³	5'-gAC ³	5'-ACT ³	5'-ACT ³	5'-ACg ³	5'-gA T ³	5'-gT C ³	5'-CCC ³	5'-CA g ³	5'-CT A ³	5'-C AT ³
								34							
								5'-Ag g ³							
160	160	75	52	1 st in	52	47	-13	1	138	69	174	139	160	208	139
5'-AgC ³	5'-AgA ³	5'-g AC ³	5'-TCT ³	5'-TgC ³	5'-TCT ³	5'-ACA ³	5'-ggC ³	5'-TTT ³	5'-T gA ³	5'-TgT ³	5'-TC g ³	5'-gCg ³	5'-AgA ³	5'-gCA ³	5'-A gA ³
								79							
								5'-gCA ³							
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Well No.															
DQA1 allele ⁴															
							24								
							24								
							24								
							24								
							24								
							24								
							24								
							24	25							
							w								
							24								
							24								
							24								
						23	24								
						23	24								
						23	24	26							
						23	24	27							
						23	24			28					
17		19					24								
?	?	19		?			?								
	18	19					24								
?	?		20	?			?								
17		19		21											
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Well No.															

Lot No.: **16F**

Lot-specific Information

Length of spec.	145	170	145	170	220	100	95	65	175	185	215	225	225	125	165	90
PCR product																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*0506								8					13	14	15	
*0507								8					13	14	15	
*0508								8					13	14	15	
*0509								8					13	14	15	
*060101-060102								8					13			
*0602								8					13			
DQA1 allele ⁴																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQA1 typing.

In addition, wells number 2, 12, 13 and 22 contain the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.



Lot No.: **16F**

Lot-specific Information

200	200	205	130	110	120	85	240	175	150	90	105	160	215	100	135	Length of spec.
								275								PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
	18	19					24						30			*0506
	18	19					24							31		*0507
17		19		21											32	*0508
17		19		21				w								*0509
					22	23	24									*060101
					22	23	24					29				*0602
																DQA1 allele ⁴
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

²The codon, in the 1st, 2nd, 3rd or 4th exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

³The codon, in the 1st, 2nd, 3rd or 4th exon or the 1st intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given. Empty spaces indicate codon boundaries.

⁴The sequence of the DQA1*030102 allele has been shown to be identical to DQA1*0302. DQA1*050103 has been renamed to DQA1*0505.

⁵Primer mix 25: Specific PCR product of 175 bp in the DQA1*0107 allele. Specific PCR product of 275 bp in the DQA1*0509 allele.

⁶Primer located upstream of the 1st exon.

'w', may be weakly amplified.

'?', nucleotide sequence information not available for the primer matching sequence.



Lot No.: **16F**

Lot-specific Information

CELL LINE VALIDATION SHEET																				
DQA1 SSP typing kit																				
					Well															
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200629101	200629102	200629103	200629104	200629105	200629106	200629107	200629108	200629109	200629110	200629111	200629112	200629113	200629114	200629115	200629116
	IHCW cell line		DQA1*																	
1	9001	SA	*0101		+	+	-	-	-	-	-	+	-	-	-	-	+	-	-	-
2	9280	LK707	*0103	*0303	-	-	+	+	-	-	-	+	-	+	-	+	+	-	-	-
3	9011	E4181324	*0103		-	-	+	+	-	-	-	+	-	-	-	-	+	-	-	-
4	9275	GU373	*0501		-	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-
5	9009	KAS011	*0102		-	+	+	-	-	-	-	+	-	-	-	-	+	-	-	-
6	9353	SM	*0103	*0301	-	-	+	+	-	-	-	+	-	+	-	-	+	-	-	-
7	9020	QBL	*0501		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
8	9007	DEM	*0303	*0102	-	+	+	-	-	-	-	+	-	+	-	+	+	-	-	-
9	9026	YAR	*0301		-	-	-	-	-	-	-	+	-	+	-	-	+	-	-	-
10	9107	LKT3	*0303		-	-	-	-	-	-	-	+	-	+	-	+	-	-	-	-
11	9051	PITOUT	*0201		-	-	-	-	-	-	-	+	+	-	-	-	+	-	-	-
12	9052	DBB	*0201		-	-	-	-	-	-	-	+	+	-	-	-	+	-	-	-
13	9067	BTB	*0401		-	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-
14	9071	OLGA	*0401		-	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-
15	9075	DKB	*0302		-	-	-	-	-	-	-	+	-	+	+	+	-	-	-	-
16	9037	SWEIG007	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
17	9008	WILJON	*0102		-	+	+	-	-	-	-	+	-	-	-	-	+	-	-	-
18	9257	32367	*0102	*0303	-	+	+	-	-	-	-	+	-	+	-	+	+	-	-	-
19	9038	BM16	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
20	9059	SLE005	*0102		-	+	+	-	-	-	-	+	-	-	-	-	+	-	-	-
21	9064	AMALA	*0503		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
22	9056	KOSE	*0102	*0104	+	+	+	-	+	+	-	+	-	-	-	-	+	-	-	-
23	9124	IHL	*0103	*0104	+	+	+	+	+	+	-	+	-	-	-	-	+	-	-	-
24	9035	JBUSH	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
25	9049	IBW9	*0201		-	-	-	-	-	-	-	+	+	-	-	-	+	-	-	-
26	9285	WT49	*0501		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
27	9191	CH1007	*0303	*0105	+	+	-	-	+	-	-	+	-	+	-	+	+	-	-	-
28	9320	BEL5GB	*0201	*0303	-	-	-	-	-	-	-	+	+	+	-	+	+	-	-	-
29	9050	MOU	*0201		-	-	-	-	-	-	-	+	+	-	-	-	+	-	-	-
30	9021	RSH	*0401		-	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-
31	9019	DUCAF	*0501		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
32	9297	HAG	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
33	9098	MT14B	*0301		-	-	-	-	-	-	-	+	-	+	-	-	+	-	-	-
34	9104	DHIF	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
35	9302	SSTO	*0301		-	-	-	-	-	-	-	+	-	+	-	-	+	-	-	-
36	9024	KT17	*0301		-	-	-	-	-	-	-	+	-	+	-	-	+	-	-	-
37	9065	HHKB	*0103		-	-	+	+	-	-	-	+	-	-	-	-	+	-	-	-
38	9099	LZL	*0503		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
39	9315	CML	*0303	*0501	-	-	-	-	-	-	-	+	-	+	-	+	+	+	+	-
40	9134	WHONP199	*0201	*0302	-	-	-	-	-	-	-	+	+	+	+	+	+	-	-	-
41	9055	H0301	*0102		-	+	+	-	-	-	-	+	-	-	-	-	+	-	-	-
42	9066	TAB089	*0103		-	-	+	+	-	-	-	+	-	-	-	-	+	-	-	-
43	9076	T7526	*0302		-	-	-	-	-	-	-	+	-	+	+	+	-	-	-	-
44	9057	TEM	*0104		+	+	-	-	+	+	-	-	-	-	-	-	+	-	-	-
45	9239	SHJO	*0201	*0303	-	-	+	+	-	-	-	+	-	+	-	+	+	-	-	-
46	9013	SCHU	*0102		-	+	+	-	-	-	-	+	-	-	-	-	+	-	-	-
47	9045	TUBO	*0505		-	-	-	-	-	-	-	+	-	-	-	-	+	+	+	-
48	9303	TER-ND	*0101		+	+	-	-	-	-	-	+	-	-	-	-	+	-	-	-

Lot No.: **16F**

Lot-specific Information

CELL LINE VALIDATION SHEET																				
DQA1 SSP typing kit																				
					Well															
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
				Prod. No.:	200629117	200629118	200629119	200629120	200629121	200629122	200629123	200629124	200629125	200629126	200629127	200629128	200629129	200629130	200739831	200611332
	IHWC cell line		DQA1*																	
1	9001	SA	*0101		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
2	9280	LK707	*0103	*0303	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
3	9011	E4181324	*0103		-	-	-	-	-	-	-	+								
4	9275	GU373	*0501		+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
5	9009	KAS011	*0102		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
6	9353	SM	*0103	*0301	-	-	-	-	-	-	-	+								
7	9020	QBL	*0501		+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
8	9007	DEM	*0303	*0102	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
9	9026	YAR	*0301		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
10	9107	LKT3	*0303		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
11	9051	PITOUT	*0201		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-
12	9052	DBB	*0201		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-
13	9067	BTB	*0401		-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-
14	9071	OLGA	*0401		-	-	-	-	-	-	+	+								
15	9075	DKB	*0302		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
17	9008	WILJON	*0102		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
18	9257	32367	*0102	*0303	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
19	9038	BM16	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*0102		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
21	9064	AMALA	*0503		-	+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
22	9056	KOSE	*0102	*0104	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
23	9124	IHL	*0103	*0104	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
24	9035	JBUSH	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*0201		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-
26	9285	WT49	*0501		+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
27	9191	CH1007	*0303	*0105	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*0201	*0303	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
29	9050	MOU	*0201		-	-	-	-	-	-	-	W	-	-	-	-	-	-	-	-
30	9021	RSH	*0401		-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-
31	9019	DUCAF	*0501		+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
32	9297	HAG	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*0301		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
34	9104	DHIF	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*0301		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
36	9024	KT17	*0301		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
37	9065	HHKB	*0103		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
38	9099	LZL	*0503		-	+	+	-	-	-	-	+	-	-	-	-	-	-	-	-
39	9315	CML	*0303	*0501	+	-	+	-	-	-	-	+	-	-	-	-	-	-	-	-
40	9134	WHONP199	*0201	*0302	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
41	9055	H0301	*0102		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
42	9066	TAB089	*0103		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
43	9076	T7526	*0302		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
44	9057	TEM	*0104		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
45	9239	SHJO	*0201	*0303	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
46	9013	SCHU	*0102		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
47	9045	TUBO	*0505		+	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*0101		-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-

Lot No.: **16F**

Lot-specific Information

CERTIFICATE OF ANALYSIS

Olerup SSP® DQA1 SSP

Product number: 101.231-24u/04u – without *Taq* pol.
Lot number: 16F
Expiry date: 2010-October-01
Number of tests: 24 tests – Product No. 101.231-24u
4 tests – Product No. 101.231-04u
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2006-291-01	13	2006-291-13	25	2006-291-25
2	2006-291-02	14	2006-291-14	26	2006-291-26
3	2006-291-03	15	2006-291-15	27	2006-291-27
4	2006-291-04	16	2006-291-16	28	2006-291-28
5	2006-291-05	17	2006-291-17	29	2006-291-29
6	2006-291-06	18	2006-291-18	30	2006-291-30
7	2006-291-07	19	2006-291-19	31	2007-398-31
8	2006-291-08	20	2006-291-20	32	2006-291-22
9	2006-291-09	21	2006-291-21		
10	2006-291-10	22	2006-291-22		
11	2006-291-11	23	2006-291-23		
12	2006-291-12	24	2006-291-24		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions No. 7, 16, 20 and 25 to 32 were available. In primer solutions 7, 25, 26, 29, 31 and 3 the 5'-primers were tested by adding one additional 3'-primer, the 3'-primers were not possible to test. In prime solutions 16, 20, 27, 28 and 30 the 3'-primers were tested by adding one additional 5'-primer, the 5'-primers were not possible to test.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2009-May-26

Approved by:

Quality Control, Supervisor

Lot No.: **16F**

Lot-specific Information

Declaration of Conformity

Product name: *Olerup* SSP® DQA1

Product number: 101.231-24u/04u

Lot number: 16F

Intended use: HLA-DQA1 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Hasselstigen 1
SE-133 33 Saltsjöbaden, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2000, ISO 17025:1999 and ISO 13485:2000, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

The Technical Construction File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Saltsjöbaden, Sweden
2009-May-26

Olle Olerup
Managing Director



Lot No.: **16F**

Lot-specific Information

Lot No.: **16F**

Lot-specific Information

Lot No.: **16F**

Lot-specific Information

ADDRESSES:

Manufacturer:

Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

Tel: +46-8-717 88 27

Fax: +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: <http://www.olerup.com>

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00

Fax: +43-1-710 15 00 10

E-mail: support-at@olerup.com

Web page: <http://www.olerup.com>

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1

Fax: 610-344-7989

E-mail: info.us@olerup.com

Web page: <http://www.olerup.com>

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.